

K121664 T4/T5 HYTREL TOGASMar 10, 2014
643 days to decisionK121664 · Product code: **FYA** · General Hospital
Source: <https://www.510kdatabase.net/k121664/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Jun 5, 2012
Decision date	Mar 10, 2014
Days to decision	643 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Stryker Corporation
Location	Malwah, NJ, US
Contact	CASEY A METZGER
Website	http://www.stryker.com/
510(k) history	81 submissions · 81 cleared · 2010-2023

Stryker Corporation is an American multinational medical technology company headquartered in Portage, Michigan. The company develops and markets surgical equipment, neurotechnology, orthopedic implants, and patient safety systems used globally across medical specialties. Stryker has received FDA 510(k) clearances from total submissions between 2010 and 2023. The company's cleared devices span orthopedic surgery, neurosurgery, general and plastic surgery, and ear, nose, and throat specialties. This regulatory record reflects the company's broad portfolio across surgical an...
